spaced apart relationship with said generally horizontal surface.

24. (New) The test device according to claim 1 wherein said testing assembly comprises a plurality of spaced apart test strips each communicating with said sample metering means.

REMARKS

Original claims 2-20 have been canceled, claim 1 amended and claims 21-24 added to more clearly define the present invention.

Support for the amendment to claim 1 and the added claims may be found in the original specification beginning on page 10, line 12.

In addition, claim 1 has been amended to overcome the rejection of original claim 1 under 35 USC 112 by the Examiner with regard to vague and indefinite terminology. The Examiners terminology has been adopted in that the "pocket portion" is now defined as a "chamber". Corresponding amendment to the specification has been made to correlate same with the amended claims. The Applicants submit that the present amendment to the claims overcome the Examiners rejection under 35 USC 112, second paragraph.

The original claims have been rejected by the Examiner under 35 USC 102(b) as being anticipated by U.S. 5,559,041 to Kang, et al., U.S. 5,656,503 to May, U.S. 5,798,273 to Shuler, et al., U.S. 6,027,943 to Kang, et al., U.S.

5,468,648 to Chandler, U.S. 5,202,268 to Kuhn, et al., U.S. 5,976,895 to Chipowski and U.S. 6,203,757, Lu, et al.

The Applicants submit that this rejection of claims under 35 USC 102(b) is moot in view of the present amendment to the claims and the newly added claims.

Specifically, the present invention now defines an analytical test device as including a sample metering means for controlling a release rate of fluid sample from the pocket with the sample metering means comprising a sample pad and a feed element having a generally planar surface pressed against the sample pad and at least one feet inlet through the planar surface. As pointed out in the specification on page 10, beginning at line 16, the generally planar surface 56 is in contact with and provides pressure against the sample pad 28. The structure of the freed element 52 and the pressure thereof against the sample pad 52 provides a means for automatic control specimen metering of fluid specimen from the pocket and onto the sample pad 28 after the device 10 is manually dipped into the test fluid. This pressure and combination with the feed inlets 58 provide for a metering of fluid not disclosed in a structure or function in any of the prior art cited by the Examiner.

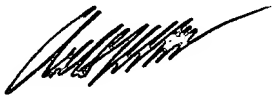
The Applicants submit that anticipation is established only when a single prior art referenced discloses each and every element of the claimed invention. RCA Corp. v. Applied Digital Data Systems, Inc. 221 USPQ 385 (Fed. Cir. 1994).

The Applicants submit that it must be clear that none of the references cited by the Examiner teach the structure now claimed by the Applicants which functions in a manner similar to that of the Applicants for providing a resulting metered output of fluid sample from a collection pocket.

In view of the arguments hereinabove set forth in amendment to the claims and specification, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Respectfully submitted,



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(DATE SIGNED)

WALTER A. HACKLER
REG. NO. 27,792

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

The paragraph on page 8, beginning at line 6, has been replaced by the following paragraph:

The casing 12 may be made of any suitable material ~~or materials of manufacture,~~ such, for example, plastic ~~as plastics material~~ with the cover 14 and base 16 being molded separately and thereafter fastened together in a tight fit to ensure security against ingress of fluid through seams of the casing 12. Preferably, the cover 14 and base 16 are sonically welded together in order to provide a fluid tight seal therebetween.

The paragraph on page 9, beginning at line 29 has been replaced by the following paragraph:

Referring now particularly to Figures 1 and 4, the casing 12 includes a ~~pocket portion~~chamber 42 and an observation portion 44. More specifically, the ~~pocket portion~~chamber 42 defines a pocket 48 sized and adapted to contain a predetermined volume of a fluid sample. The pocket 48 is sized for containing a predetermined volume of fluid specimen necessary to run all of the test elements 22 to completion following quick momentary submersion into the test fluid. As a specific example, device 10 is adapted to accommodate five test elements 22 and each test element 22 requires about 50 microliters (which is about one drop) of fluid (e.g. urine) for completion. Consideration is of course given to the small volume of fluid that will

naturally be retained by the sample pad 28. The pocket 48 in this example is sized to contain about 0.3 mL (i.e. 300 microliters) of urine.

The paragraph on page 10, beginning at line 12, has been replaced by the following paragraph:

Importantly, the ~~pocket portion~~chamber 42 further defines a feed element 52, shown in Figures 4 and 5. As shown in Figure 5, the cover 14 and base 16 define a generally hollow cavity 54 in which the testing assembly 18 is disposed. The feed element 52 is defined by an interior surface 55 of the casing cover 14. Referring now briefly to Figure 4, the feed element 52 includes a generally planar surface 56. Turning as well to Figure 6, the generally planar surface 56 is in contact with and importantly, provides pressure against the sample pad 28. Advantageously, the structure of the feed element 52 and the pressure thereof against the sample pad 28 feature provides means for automatic controlled specimen metering of the fluid specimen from the pocket 48 and onto the sample pad 28, after the device 10 is manually dipped (preferably for a maximum duration of between about one second and about five seconds) into the test fluid.

The paragraph on page 12, beginning at line 10 has been replaced by the following paragraph:

The appropriate volume of fluid sample for running the test may be deposited in the pocket 48 by simply dipping the ~~pocket portion~~chamber 42 of the device 10 into a fluid collection cup (not shown) containing a urine specimen. No

precise timing is necessary. A brief one second to about five second dip assures that the appropriate volume of test fluid will be deposited in the pocket 48.

The paragraph on page 14, beginning at line 27, has been replaced by the following paragraph:

More particularly, once a specimen has been collected in a collection cup (not shown), for example after a test subject has filled a collection cup with urine, the technician or analyst can perform the entire assaying procedure by grasping the device 10 by contours 64 and finger grip 66 and dipping the device 10 into a fluid specimen, at least up to a "fill-line" 98 (see Figure 1), but not as far as the observation windows 72. After briefly dipping the device 10 in the specimen, the device 10 may then be touched to an edge of the collection container to remove any droplets of urine adhering to the casing 12, particularly on the dipped portion (i.e. ~~pocket portion~~chamber 42) of the casing 12. The device 10 having the pocket 48 filled with the fluid specimen~~,~~ is then placed on the table or counter top 88 in the horizontal position, such as shown in Figure 5.

The paragraph on page 15, beginning at line 9, has been replaced by the following paragraph:

Advantageously, the damp or wet portion (i.e. ~~pocket portion~~chamber 42) of the device 10 is supported above and out of contact with the table or counter top 88 by means of the rail 84 depending from the base 16. This feature is designed to enhance laboratory efficiency and cleanliness,

particularly in a laboratory where frequent and numerous assaying tests must be performed on a limited work space and within a short time period. For example, a potential time savings may be realized by minimizing work surface contamination since the fluid specimen is kept completely out of contact with the work surface even though the device is placed directly on the work surface as shown. It can be appreciated by those of skill in the art that the assaying device 10 in accordance with the invention is designed to contributes to a cleaner, more sanitary work area than conventional dip-and-read devices which require either the device be manually held during the testing procedure, hooked on the collection container, or placed in a wet condition on a work surface.

IN THE CLAIMS

Claims 2-20 has been canceled, claim 1 has been amended and claims 21-24 have been added as follows:

1. (Amended) An analytical test device comprising:

a casing, including a ~~pocket portion~~chamber defining a pocket sized to contain a predetermined volume of a fluid sample; ~~and further defining a feed element~~

sample metering means for controlling a release rate of fluid ~~specimen release~~sample from the pocket, said sample metering means comprising a sample pad and a feed element having a generally planar surface pressed against said sample pad and at least one feed inlet through the planar surface; and

a testing assembly, disposed in the casing, for assaying the released fluid sample ~~contained in~~from the pocket.

21. (New) The test device according to claim 1 wherein the at least one feed inlet comprises a plurality of spaced apart feed inlets in said generally planar surface.

22. (New) The test device according to claim 1 wherein the at least one feed inlet comprises a slot in said generally planar surface.

23. (New) The test device according to claim 1 further comprising means for supporting said casing in a generally horizontal surface with the chamber disposed in a spaced apart relationship with said generally horizontal surface.

24. (New) The test device according to claim 1 wherein said testing assembly comprises a plurality of spaced apart test strips each communicating with said sample metering means.

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